Machine Learning Applications in Healthcare and the Role of Informed Consent: Ethical and Practical Considerations

Abstract

Informed consent is at the core of the clinical relationship. With the introduction of machine learning (ML) in healthcare, the role of informed consent is challenged. This paper addresses the issue of whether patients must be informed about medical ML applications and asked for consent. It aims to expose the discrepancy between ethical and practical considerations, while arguing that this polarization is a false dichotomy: in reality, ethics is applied to specific contexts and situations. Bridging this gap and considering the whole picture is essential for advancing the debate. In the light of the possible future developments of the situation and the technologies, as well as the benefits that informed consent for ML can bring to shared decision-making, the present analysis concludes that it is necessary to prepare the ground for a future requirement of informed consent for medical ML.

Keywords

Ethics, Healthcare, Informed Consent, Machine Learning, Shared Decision-Making, Transparency.

Introduction

Informed consent is almost a novelty in medical practice. While the earliest form of medicine can be dated up to 2500 years ago, with the inception of the Hippocratic Oath [1], the first mention of informed consent was in 1957[2]. Another important milestone in the history of informed consent is the Declaration of Helsinki, originally adopted in 1964. Although the Declaration focuses on medical research rather than clinical practice, it has been pivotal for disseminating the concept of informed consent in healthcare. Several controversial human experiments and clinical practices have since brought the debate about informed consent to a wider public. In response, bioethics became an increasingly relevant discipline and various approaches to navigate challenging ethical dilemmas have been proposed. One of such approaches are the four bioethical principles enunciated by Beauchamp and Childress [3]: respect for autonomy, beneficence, non-maleficence, and justice. These principles became crucial in the subsequent bioethical considerations. Although this paper does not intend to adopt Beauchamp and Childress' approach to address the current issue, it aims to highlight the special role of the principle of respect for autonomy when it comes to reflect on informed consent. Autonomy is closely linked with informed consent, which aims to protect and promote patients' autonomy. While the four principles are intended to be equally important, particular emphasis is given to the principle of autonomy in modern healthcare.

It is necessary to elucidate further the concept of informed consent to better grasp its centrality in the contemporary bioethical debate. Informed consent is a process required for clinical practice and research with human subjects. The practitioner informs the patient, in a simple and understandable language, about the procedure and associated risks and benefits, possible alternatives, prognosis, and consequences of each clinical decision [4–6]. It is difficult to define the details of what ought to be disclosed; generally, clinicians need to disclose everything that a reasonable patient would want and need to know to understand their clinical situation and consequentially make an informed decision [5,7–9]. However, this rule is very broad – what matters varies depending on the case – and can still result in paternalism since it is the clinician who decides which information is indispensable [10]. This highlights the asymmetry of power and information between doctors and their patients. It is therefore necessary to carefully assess and evaluate informed consent in order to preserve patients' autonomy, self-determination and inviolability [11]. Simply signing a form does not guarantee that informed consent is valid [12,13]; instead, it is necessary to ensure that information is understood and that patients can participate in the decision-making process [14]. To ensure this, sensitive and effective doctor-patient communication is crucial.

Informed consent has two major functions in the clinical context. First, it waives ethical and legal norms prohibiting invasive interventions, ensuring that patients understand and agree to the mentioned intervention, thus seeking to avoid patients' abuse and manipulation. At the same time, informed consent fosters *shared decision-making* (SDM). SDM can be defined as a mutual agreement between doctors and patients that takes into account both doctors' expertise and patients' preferences [6,15]. Regarding the first function, patients consent to practices that would otherwise be prohibited and would result in the prosecution of the doctor: consent is not required for actions that do not violate ethical or legal norms, and are therefore already permissible [10]. For example, clinicians are not expected to seek consent when asking patients how they are feeling, instead, they should do so when administering drugs or performing surgery because the ethical and legal norms regarding the inviolability of the human body and personal freedom may otherwise be infringed [10]. Contemporarily, informed consent is used to reach decisions shared between the doctor and the patient. According to the SDM paradigm, both parties are experts: doctors are experts in medicine, while patients are experts in their values [16]. The common ground for SDM is informed consent: the doctor discloses what is deemed as necessary information, and answers the patient's questions honestly. At the same time, patients disclose information regarding their preferences and their values. The goal is to allow and motivate patients to be more involved in their own healthcare [17]. It is commonly argued that SDM promotes a more ethical medical practice while improving the quality of care; therefore, it can be considered as the ethically appropriate paradigm[18–20].

After this brief and non-exhaustive elucidation of informed consent, it is time to introduce the second main theme of this paper: *machine learning* (ML). ML is a type of artificial intelligence that is able to learn from data and become more accurate, improving its performance [21,22]. In healthcare, ML can be used as *clinician decision support system* (CDSS) for its predictive capabilities; it provides recommendations and diagnoses for a wide range of situations. However, ML applications in healthcare generates concern because

of the problem of the black box: although developers understand the process by which ML generates new models, the models themselves are inscrutable to humans, hence they are black boxes [23]. Black boxes generate concern since they can prevent causal insights of ML's outputs. In the worst-case scenario, doctors are confronted with ML's recommendations with which they do not agree and that they do not understand, and cannot understand unless the ML provides any sort of justification or reason for its output.

The introduction of ML in clinical practice challenges the boundaries of informed consent and raises a panoply of questions. First of all, are doctors required to disclose to patients that their decisions are supported by ML? Should they invest their time explaining to patients information that they, in the first place, may not completely understand? Or is ML simply another tool amongst the others that doctors are not required to disclose? What would be the purpose of disclosing ML usage? The present discussion aims to present the discrepancy between many of the arguments found in the literature: often a more theoretical or more practical stance is inadvertently taken and the conclusions largely rely on the chosen angle. By bringing to light this tension between practical and ethical considerations, the goal is to position the issue in the frame of possible future developments, while attempting to bridge the gap.

Ethical considerations

Transparency can be conceived as a condition that often endorses or enables ethical practices [24], such as informed consent. In this paper, transparency is intended as doctors honestly disclosing information to their patients. Accordingly, transparency is necessary, even if not sufficient, to achieve informed consent. This is valid in clinical practice as well: it is generally thought that doctors that are transparent with their patients have more ethical conduct than the ones that are not. Like almost everything in ethics, transparency needs to be balanced: there are some cases in which clinicians may find transparency a constraint and disclosure would bring little or even no good. Therefore, one should ask whether clinicians should be required to be transparent with patients about ML usages.

One preliminary question is the reason for disclosing this information to patients [25]. The ultimate goal of the disclosure can justify the expenditure of resources for informing patients about medical ML. Since transparency is positively linked with informed consent, which in turn is linked with SDM, it is possible to conclude that disclosing ML usages to patients is ethically recommended when it promotes SDM. This is because SDM is considered to be the ethically appropriate paradigm for the doctor-patient relationship [18]. Being transparent about ML employment can be beneficial for SDM to take place while ensuring trust and setting up a solid base for communication to take place. Disclosing all relevant information is essential for SDM to succeed, and ML outcomes can be relevant for the role they play in clinical assessment. Interviews with patients on SDM have revealed that "shared decision making is hard because [doctors] have so much more knowledge. So it can't be totally shared unless we are totally informed" [19]. To facilitate patients' involvement in the SDM process, it is therefore extremely important to provide them with complete information. Although not all patients intend to actively participate in the decision-making process, and some

prefer to leave the final decision to doctors, nearly all patients wish to be informed, given options, and asked for their preferences [19,26]. Ultimately, when faced with the question of whether to disclose or not medical ML usages, one should try to understand what is the reason for disclosing. In cases where disclosing can empower patients and foster better communication to reach a shared decision, it is ethically advisable to do so. If transparency about ML leads to patients being better informed and hence better positioned to participate in the decision-making process, ethical considerations favour the extension to informed consent requirements to ML.

Unfortunately, it is not always so simple, but before coming to the objections let us consider another ethical argument in favour of disclosing ML to patients. ML employed as CDSS influences clinicians' decisions to the point where the extent to which it influences their judgement is debatable [27,28]. Indeed, ML suggestions may prompt practitioners more than they are aware [28]. This influence generates concern, especially regarding human control and autonomy. When ML is used to support doctors' decisions, some of the decision-making power is ceded to the algorithm [29]. It is therefore of the foremost importance to balance human decision-making with ML-led decisions to avoid arbitrary decision-making. Accordingly, most experts argue for maintaining human agency, responsibility, control, and oversight over ML systems [27,29–31]. Continuous supervision, overview, and control by human agents shall ensure that ML is not a stand-alone system: it is rarely[1] the case that ML decisions are not considered by a clinician before they are accepted or refused. Hence the final decision can be conceived as shared between ML and doctors. On the other hand, disclosing ML usages to patients and discussing these suggestions with them could augment the human factor in the decision-making process, thus guaranteeing a larger amount of human scrutiny. Moreover, this would enable patients to participate in the decision-making process, hence making the final decision shared between ML, doctors, and patients. Although this tactic alone cannot preserve human control and autonomy, it could be part of a larger strategy for balancing human and ML decision-making power.

The principle of respect for autonomy and informed consent are closely linked: one of the aims of informed consent is to help protect and promote patients' autonomy. For example, patients' autonomy is preserved when they are enabled to decide whether to undergo a certain medical treatment or not. Therefore, the opt-out option is an essential part of respecting patients' autonomy; at the same time, patients need to be informed in order to opt-out. This is true also with medical ML: being unaware of its use, patients are not given the choice of whether to opt-in or opt-out. Their personal health data is being fed to ML without seeking their consent and hence without respecting their preferences. This can have detrimental consequences on their autonomy. Introducing informed consent for ML usages in healthcare allows patients to decide on their health data, which is perceived as one of the most sensitive types of data [32].

These three arguments in favour of introducing informed consent for medical ML have in common a theoretical stance, meaning that they do not acknowledge the practical difficulties and obstacles involved in implementing this requirement. The present limitation might be caused by the complexity of the issue: an

[1] There are some exceptions, such as the *IDx-DR*, the first autonomous FDA-authorized AI diagnostic system for diabetic retinopathy and macular enema.

interdisciplinary appraisal is needed to appraise the legal implications, the ethical consequences, and the reality of clinical practice. However, interdisciplinary perspectives can be difficult to attain[33,34].

Nonetheless, not all theoretical arguments are in favour of extending the informed consent requirement to medical ML. For example, the debate over the ontology of ML – whether ML is a tool, like many others employed in everyday medical practice, or if is it something different – can offer a ground for denying the need for informed consent. If ML was simply another tool that clinicians use during their decision-making process, it could be argued that not informing patients does not conflict with ethical and legal requirements. Since it is generally not required for doctors to disclose how tools influence their decisions, many do not see any logic in imposing this type of obligation for ML. Therefore, failing to inform patients about ML uses would not violate the doctrine of informed consent [35].

However, the idea that ML is a mere tool does not come without controversies. A major argument regarding ML not being a traditional tool is the problem of the black box: the inherent opaqueness of its algorithms may differentiate it from other tools, whose mechanisms are usually transparent. In contrast with other tools, ML is inaccessible to doctors' scrutiny, and its causal insights remain hidden. For this reason, some experts fear that doctors may become less the deciders, and more the implementers of ML outputs [18,27]. Other doubts about ML classification as a tool are raised by its suggestions, which can influence clinicians' decisions more than they think (similarly to a nudge rather than a simple suggestion)[28]. The extensiveness of ML's influence could differentiate it from other tools, which generally do not present this feature. Lastly, the idea that ML does not violate ethical and legal requirements can be questioned as well: ML entails many risks as it can make widely incorrect evaluations and its recommendations tainted by discriminatory bias [31,36,37].

Suggesting that ML does not violate any fundamental ethical or legal requirement may be naïve considering the novelty of its applications: the consequences of its widespread application in healthcare still have to be identified and assessed. The risks posed by ML must not be overlooked; instead, there is the need to conduct further research – for example, some CDSS are not well integrated into clinical practice, require doctors to invest their limited time in inputting data into the system, and present too many alerts that eventually doctors ignore[38]; ML can lead to benefits as well as burdens for the healthcare sector. In the future, we might be more aware of the risks it entails and therefore the stance towards the necessity of informed consent for medical ML may differ accordingly. As of now, the heated debate on ML ontology remains open.

Practical considerations

The previous ethical analyses should be considered in light of the available resources. Transparency about ML applications may not always be the best option, and doctors that choose not to do so must not be immediately judged as unethical. There can be variety of reasons why doctors do not disclose ML to patients. First of all, doctors already have a tight schedule and it is sometimes challenging to take the time to discuss ML usages and its suggestions with patients. If the process of SDM was to be made more complex, in some circumstances

this could put at risk patients' health rather than benefiting it. There is already a deficit in providing the necessary information to patients [5]. This is in part due to the already-existing barriers clinicians encounter when communicating with patients, which include time constraints [39]. Many practitioners maintain that obtaining informed consent every time ML is used is very time-consuming and could take up time from the conversation about care [31]. Doctor-patient communication must prioritize health-related discussions; when informing the patients about ML derails the dialogue from this priority, disclosing could potentially be harmful [31]. Nevertheless, time-constraint barriers could be overcome with the automation of parts of doctors' workload with ML, hence reducing the burden of routine tasks [40]. However relevant, the time-constraint objection is not categorical since ML itself could invalidate it. As ML takes over clinical routine tasks, doctors can have more time to invest in communicating with patients. Eventually, the time-constraints preventing doctors from discussing ML usages with patients could be resolved by ML itself.

It must not be assumed that all clinicians have a meaningful understanding of ML, hence it would put them in a difficult position if they had to disclose and answer patients' questions about ML. In addition to doctors who do not understand how ML works, some patients are technologically illiterate, sometimes to the extent that any comprehension of ML functions is denied to them. The lack of understanding of ML can represent a difficulty in the practical implementation of informed consent. On the other hand, doctors can be trained and educated, allowing them to learn about ML to the extent necessary to safely use it and, at the same time, to be able to discuss it with patients. It is probably not necessary for doctors to have exhaustive knowledge of ML – for instance, knowledge on ML programing or on its mathematical constructs. In reality, doctors need enough information to assess the technology and comprehend its impact on patients. With this information, doctors may be better positioned to address patients' issues and find the best tailored solution for them. At the same time, patients can be taught as well. Moreover, it can be reasonably expected that in the future humans will be more and more acquainted with this kind of technology, hence gaining better insights and some general knowledge on its functioning. Increased familiarity with ML could be pivotal for the success of any eventual future requirement for informed consent.

Bridging the gap

On the one hand, many ethical arguments favour the implementation of informed consent for ML applications in healthcare. On the other hand, the majority of the practical considerations focus on the difficulties of imposing this requirement for everyday clinical practice. However, there is an exigency – as well as a possibility – to find common ground to further advance the debate. The first step is to bear in mind that this polarization between ethical and practical considerations is not a real distinction: in clinical practice, ethics is applied to specific contexts and situations, and hence considers practical barriers and enablers. Although the debate on ML informed consent seems to be split into these two distinct viewpoints, in reality they overlap and cooperate.

A second reason for surmounting the polarization is that some theoretical arguments argue against the implementation of informed consent for ML. At the same time, there are practical considerations in favour of an informed consent requirement for ML. As previously discussed, disclosing ML to patients may divert time from the conversation about care, which could result in lower quality of care and diminished SDM for patients. A doctor communicating about ML could mean that, although the patient has the possibility to opt in or out, their doctor may not have time to discuss other important information, such as alternative treatment. As a consequence, the patients would not be able to participate fully in the treatment decision, resulting in non-ideal clinical practice. At the same time, transparency about ML could foster patients' trust and ameliorate the doctor-patient relationship. This may correlate with better SDM and consequently with improved quality of care[9,16].

The previous examples blur the boundaries of the distinction between a theoretical and a practical stance. Ethical arguments are based on practical circumstances and defined contexts, while practical reflections are informed by ethical principles. A stark division is inconceivable and unrealistic. Of course, differentiations can be – and sometimes must be –made for the sake of the discussion: it can be easier to reason with categories. However, it is crucial to remember that in reality ethics and practice are strictly intertwined, and such a polarization between ethical and practical considerations is not possible.

Despite the lack of a legal requirement to disclose ML usage to patients and to extend the informed consent process to its applications, in the present analysis we argue that it is ethically advisable to implement informed consent for medical ML in a way that further promotes and fosters SDM. Confronted with the ethical dilemma of whether to disclose ML to patients, being transparent seems the better option, given that the SDM paradigm is widespread and well-respected. At the same time, it would not be fair to simply deem doctors that choose not to disclose ML as unethical. As there are currently many obstacles and uncertainties to the implementation of ML informed consent, not informing patients about it can be excused. However, this does not mean that one should not aim to change the situation and orient towards a better alternative – namely, informed consent for ML applications in healthcare. As has been noted previously, the objections to ML informed consent are not categorical, but rather contingent, meaning that solutions can be found. It is possible to find ways to overcome the impracticability of a requirement for ML informed consent, sometimes with the help of ML itself. The moral duty would not be that of imposing a requirement for informed consent, rather, to prepare the ground for this requirement to flourish. The current situation should be better adapted to the new context, where technologies as ML are integrated in clinical practice.

Conclusion

The discussion about informed consent for medical ML is very recent and it is linked to all the uncertainties surrounding ML uses in clinical contexts. Some arguments maintain that informing patients about ML usage in healthcare is impractical and there would be little benefit in disclosing at present. This idea is in line with the practical considerations analysed in this paper, which expose the unfeasibility of informed consent for ML.

However, these objections are contingent; hence they show the problems that should be addressed, rather than constituting structural impossibilities. Concluding that informed consent for medical ML is not necessary suggests that the whole picture has not been considered. The ethical value of disclosing ML to patients has been acknowledged: disclosing is ethically advisable when it empowers the patients and enables them to participate in the management of their care. This is to say, informed consent for medical ML is ethically desirable when it supports SDM.

The discrepancy between ethical and practical considerations highlights an already existing tension between ethics and practice. Recognizing and comprehending the difficulties of introducing informed consent is indispensable to overcome them. Indeed, these barriers are mostly non-structural, they do not constitute a reason for abandoning the idea of informed consent for medical ML. This is especially true when the ethical analysis illustrates the significance of doing so. It should be recognized that informed consent for ML is a requirement that may need some time before being practically feasible, and hence implemented. It might be that in future its necessity will be more evident, as the practical counter-arguments are solved and ML risks are better comprehended. Therefore, the present conclusion invites further exploration of this issue, in order to bridge and bring together ethical and practical considerations. It is now the time to prepare the healthcare sector for a future implementation of informed consent for ML applications, without compromising patient care or SDM.

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